DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

g1027d

March 9, 2001

WARNING LETTER
CHI-22-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert H. Klaus, Owner
Robert H. Klaus Farm
Route 3, Box 35
Carlinville, IL 62626

Dear Mr. Klaus:

An investigation of your swing raising operation, conducted by Mark G. Peterson, on 12/28/00, found that a hog from your establishment was offered for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (Act). The inspection also revealed significant deviations from Current Good Manufacturing Practice for Medicated Feeds, Title 21, Code of Federal Regulations, specifically Parts 225.120 through 225.202, for those facilities manufacturing solely medicated feeds for which an approved license is not required.

On or about 8/9/00, a hog was sold for slaughter as human food to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of [redacted] parts per million (ppm) sulfamethazine in the liver tissue and [redacted] ppm sulfamethazine in the muscle tissue. The established regulatory action level for sulfamethazine in swine is 0.1 ppm (Title 21, Code of Federal Regulations, Part 556.670). The presence of this drug in the edible tissue from this animal causes the food to be adulterated under the Act.

In addition, the inspection found the feeds you manufacture for your animals are adulterated within the meaning of Section 501(a)(2)(B) of the Act. Deviations noted included:

Failure to maintain Master Production records that describe feed formulation, mixing directions, and provisions for equipment cleanout.

Failure to maintain control of drug inventory.

Failure to have production records listing feed formulation; identity of amount of drug used, amount of feed produced, mix time, and distribution of finished feed.

Failure to institute adequate cleanout of mixer resulting in cross contamination of finish feed.

Failure to have adequate storage space. The drug storage area was observed to be crowded and unorganized.

No systematic method of weighing drug components was used.

The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct the violation, and you should establish procedures whereby such violation does not recur. Failure to promptly correct the violation may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes notification under the law.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Director, Compliance Branch.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Manzoor Chaudry, DVM
Branch Chief, Residue Staff
Food Safety and Inspection Service
US Dept. of Agriculture
Technical Service Center
106 S. 15th St., Ste 904
Omaha, NE 68102

cc: Richard Hull, DVM
Chief Veterinarian
Bureau of Animal Health
Division of Animal Industries
Illinois Department of Agriculture
P.O. Box 19281
Springfield, IL 62794-9281

cc: Mark Ringler
Bureau Manager
Bureau of Agricultural Products Inspection
Division of Agricultural Industry Regulations (DAIR)
Illinois Department of Agriculture
P.O. Box 19281
Springfield, IL 62794-9281